Remarks/Arguments:

This is a reply to the non-final rejection of claims 21 - 23, 25 - 31 and 41 - 42 in the office action of June 4.

The claims were rejected as obvious over a combination of the newly cited Chen et al. reference (U.S. Patent 4082881) and the previously cited Obagi et al. reference (U.S. Patent 5166176)

The rejection is respectfully reversed for the reasons set out below.

Chen et al. discloses topical and other pharmaceutical formulations containing isosorbide as a carrier.

The compositions described in Chen et al. comprise steroids as the active principal ingredient and the claimed compositions are used to treat dermatitis. No reference is made to chemical peeling.

As a consequence, the teachings contained in Chen et al. and Obagi et al. do not make it obvious to combine dimethyl isosorbide and a keratolytic agent in chemical peeling compositions.

Furthermore, Chen et al. teaches one to use dimethyl isosorbide to increase the solubility of the pharmaceutically active substances disclosed, which are steroids. So a person of ordinary skill in the art would not have learned from Chen et al. that dimethyl isosorbide (a) would enhance the solubility of the keratolytic acid contained in the present application; and (b) would ameliorate the effect of the keratolytic agent.

The preferred keratolytic agents in the compositions claimed in the present application are selected from the group consisting of saturated and unsaturated mono-, bi-and tri-carboxylic acids, as described in claim 25. The chemical features of these compounds are clearly distinct from the ones belonging to the compounds referred to in Chen et al., where reference is made to steroids. The fact that dimethyl isosorbide is used in Chen et al. to solubilize lipophilic steroids does not suggest using dimethyl isosorbide in combination with the hydrophilic keratolytic agents, as presently claimed.

Although Chen et al. discloses that dimethyl isosorbide is a solvent, is stable and is pharmaceutically acceptable for topical formulations, there is nothing in the prior art suggesting that an ameliorated peeling effect would result from a combination of a keratolytic agent and dimethyl isosorbide, to achieve the purposes of limiting, on one hand, the erythematogenous effect of the peeling composition and, and the other hand, allowing a lower content of the keratolytic agent to be included within the composition.

In support of the above argument, Applicant respectfully submits a declaration of the inventor Gianfranco de Paoli Ambrosi, in which the results of testing conducted by a university are reported and analyzed.

The documents report the results obtained for two formulations within the scope of the present claims and comprising pyruvic acid and dimethylisosorbide (Pyruvic acid ENERPEEL TECHNOLOGY 50%) (Annex 1) and glycolic acid and dimethyl-isosorbide (Glycolic acid ENERPEEL TECHNOLOGY 50%) (Annex 2), respectively.

Annex 1 is a report from the University of Catania Pharmaceutical Sciences Department, which was required to assess the peeling effect of the tested composition, i.e. Pyruvic acid ENERPEEL TECHNOLOGY 50%.

The assays were performed in comparison with compositions containing pyruvic acid only, thus lacking dimethyl isosorbide. The protocols used in order to evaluate the peeling effect as well as the induced cutaneous erythema are both disclosed in the report.

The test results are shown in Table 1 and Table 2 of Annex 1. It is fair to conclude from Annex 1 that:

1) Pyruvic acid ENERPEEL TECHNOLOGY 50% shows a stronger peeling effect with respect to Pyruvic acid only; and

2) Pyruvic acid ENERPEEL TECHNOLOGY 50%, despite the superior peeling effect, causes less irritation than a Pyruvic acid only.

Annex 2 was issued by the University of Catania Pharmaceutical Sciences Department as well and relates to a series of assays analogous to those presented in Annex 1, but wherein another composition within the present invention, comprising glycolic acid (Glycolic acid ENERPEEL TECHNOLOGY 50%), was tested.

Similarly, the protocols used for evaluating the peeling effect and the induced cutaneous erythema are reported, while the results of the tests are shown in the enclosed Figure and Tables.

The final observations in Annex 2 reported that:

1) Glycolic acid ENERPEEL TECHNOLOGY 50% shows a stronger peeling effect with respect to Glycolic acid only; and

2) Glycolic acid ENERPEEL TECHNOLOGY 50%, despite the superior peeling effect, causes less irritation than Glycolic acid only.

The Annexes demonstrate that the composition presently claimed has improved peeling effect and at the same time produces a significantly reduced cutaneous erythema with respect to compositions without dimethyl isosorbide.

Accordingly, the invention recited in claims 21 - 23, 25 - 31 and 41 - 42 is deemed to be novel and nonobvious over the cited prior art documents.

Favorable reconsideration is requested.

Respectfully submitted,

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